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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,110

12/15/2005

Sung-Teh Kim

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EXAMINER

CECIL, TERRY K

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

08/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/561,110	Applicant(s) KIM ET AL.	
	Examiner Mr. Terry K. Cecil	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/15/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following:
 - The abstract of the disclosure is objected to because it is too long (greater than 150 words).
See MPEP § 608.01(b).
 - The phrase “translucent membrane” in e.g. page 1, second paragraph, appears to be mis-translation from the original language. Did Applicant intend to claim “porous membrane”?
 - The word “polyfunctional” in e.g. page 20, last line, seems to be a mis-translation from the original language. Did Applicant intend to claim “multifunctional”?
 - The aforementioned mis-translations are not to be taken as an exhaustive list. Applicant should ensure that the entire specification has been properly translated.

Appropriate correction is required.

Drawings

2. The drawings are objected to because of the following:
 - They fail to comply with 37 CFR 1.84(p)(5) because they include the following reference signs not mentioned in the description: “17” and “18” (figure 1) and “7” (figure 3). Also, “(8)” of page 29, line 9 is not shown in the drawings.
 - They are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the means for measuring the hematocrit value of claim 33 must be shown or the feature canceled from the claims. No new matter should be entered.

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Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claim 29 is objected to because of the following:

- Claim 29, line 4, “par” should be “per”.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 1-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite because of the following reasons:

- The following terms lack antecedent basis: “the delivery means” (claim 1) and “the cycle” (claim 35).
- In claim 1, the antecedent for the phrase “which can operate in normal and opposite directions...” is unclear (the delivery means? the supply means?). For examination purposes, the antecedent is taken as being the supply means.
- Claims 2-36 are rejected since they suffer the same defects as the claims from which they depend.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

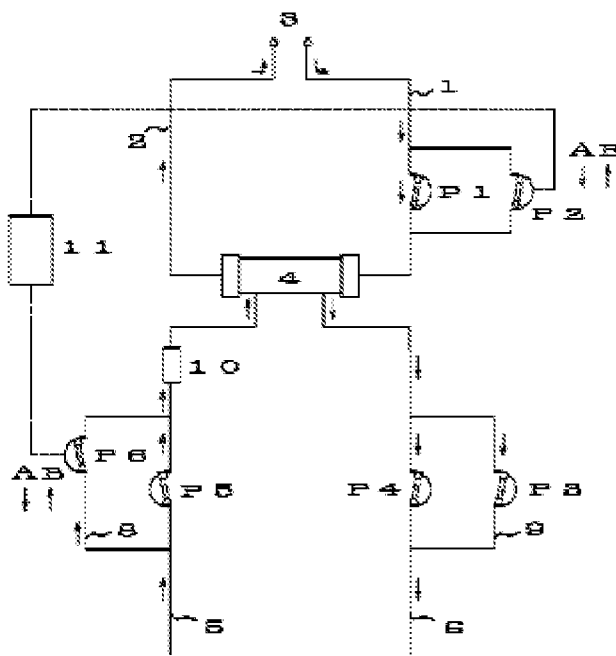
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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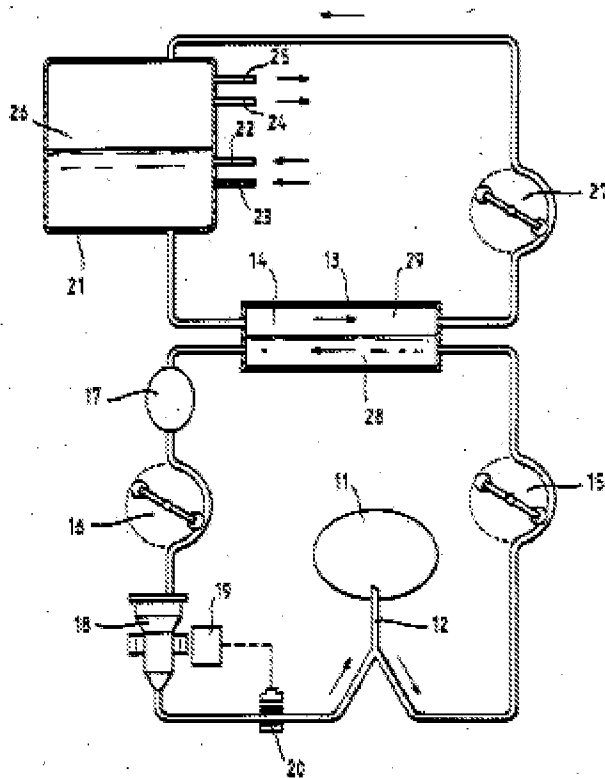
7. Claims 1-32 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 06114102A, hereinafter '102 (equivalent to JP 3277569 B2 of the ISR) in view of Chevallet, U.S. 4,599,165 (equivalent to JP 5-22549 of the ISR). '102 teaches a hemodiafiltration apparatus for extracorporeal treatment of blood, wherein the blood is extracted and reinfused; a dialysis fluid supply system and a control system.



An arterial side blood circuit directs blood from the patient 3 to a hemodialyzer 4 and a venous side blood circuit directs blood from the hemodialyzer to the patient. The arterial side includes a reversible pump P2. The dialysis fluid supply system includes a supply line 5 and a discharge line 6. The dialysis fluid supply includes a filtration/back-filtration fluid supply means P6 (a reversible pump) and a delivery means P5. The dialysis discharge means includes a water removing and fluid discharge means (P4, P5). The system includes mechanisms (abilities) to extract blood into the blood circuit and move fluid in the blood from the blood circuit to the

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dialysis supply system (filtration) and vise-versa to the patient (back-filtration). See [0005-0008]. The system also includes a plural non-continuous (repeating intermittently) mechanism for filtration/back-filtration operation (0008)[as in claim 1]. The Japanese machine translation of '102 states that the hemodialyzer includes a semi-permeable membrane of hollow fibers but doesn't specify a hollow yarn membrane. However, the hemodialyzers including hollow *yarn* fibers are well known in the art. '102 doesn't specify a system wherein the extraction and reinfusion are performed by a single needle. However, such is taught by Chevallet.



Chevallet teaches a single needle 12 for performing extractions and reinfusions [as in claim 1].

It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to have the single needle of Chevallet in the system of '102 since Chevallet teaches

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the benefit of requiring only a single access to the patient and resulting in less traumatization (col. 1).

As for claim 2, upon modification, both the blood pump and the puncture needle are taught and would be able to perform the intended use therein.

As for claim 23, '102 teaches the plurality of pumps P2, P3, P4, and P5 which are considered the claimed poly(multi)functional control means which can be controlled as desired by the control means.

As for claim 34, '102 teaches control means for pumps P2 and P6 for controlling the filtration/back filtration [0006] and also pumps P4, P5 [0008] to control dewatering and doing so based on time [0007]. Though a water removing program is not explicitly stated, programs for control means are well-known in the art for the benefit of automatic control.

Claims 3-22, 24-32 and 35-36 are geared to the ways in which the apparatus is used (e.g. method steps. Note that claim 5 even explicitly recites a "step"). It is pointed out that Applicant's claimed invention is an apparatus invention (Applicant has not claimed a method). Apparatus inventions must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. The examiner contends that upon modification, the invention of '102 in view of Chevallet includes all the structure necessary (control unit, pumps, single needle, etc) that would allow the apparatus to

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operate as claimed whether or not the specific steps are explicit in the references. See MPEP 2114.

8. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over ‘102, as modified above, and in further view of either of Ohta et al. (U.S. 6,626,857) or Davidner et al. (U.S. 7,201,730). Note that the “means for measuring the hematocrit value” of this claims is considered to be the hematocrit monitor of page 2, second paragraph of the specification or structural equivalents thereof. Both Ohta and Davidner teach a hematocrit monitor for feedback control for controlling the water removal rate (which is directly related to a measure of blood volume and pressure). It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to have the hematocrit monitor of either of Ohta or Davidner in the invention of the modified ‘102 since such would provide the benefit of preventing dehydration and hypotension of the patient or other conditions harmful to the health.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mr. Terry K. Cecil whose telephone number is (571) 272-1138.

The examiner can normally be reached on 8:00a-4:30p M-F..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Duane Smith can be reached on (571) 272-1166. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mr. Terry K. Cecil/
Primary Examiner, Art Unit 1797

tkc